

## REMARKS

Receipt of the Office Action mailed September 19, 2000 is acknowledged. The claims have been amended for clarification purposes. The claims as amended herein are fully supported by the application as originally filed. For example, see Specification p. 5-10. No new matter has been added.

Claims 1-25 are pending in the application.

In the Non-Final Office Action, the Examiner set forth a number of grounds for rejection and/or objection. These grounds are addressed individually and in detail below.

### Rejections Under 35 U.S.C. §102

Claim 25 stands rejected under 35 U.S.C. §102(b) as being anticipated by Lee et al U.S. Patent No. 3,576,433. The Examiner asserts that the Lee reference anticipates claim 25 because it discloses an electronic data process system that comprises the storing of "centralized collection of geographically distributed information" and further comprises a means for checking the integrity of the information stored. However, claim 25 is directed towards a web-enabled article of manufacture. This element is integral part of the invention because it allows the users access to clinical trial information at remote locations all over the world, almost in real time. Lee et al do not disclose or suggest transmitting the information over the Internet. Rather Lee et al merely disclose a recording-transmitting system for transmitting an order by means of acoustic signals over a standard telephone line to a receiver. Moreover, Lee et al does not disclose or suggest storing information. The electronic system disclosed in Lee uses a magnetic tape recording system. Since the Lee reference does not disclose or suggest the article of

manufacture using a web-enabled computer system, it cannot anticipate the claimed invention. Therefore, reconsideration and withdrawal of this objection is respectfully requested.

The Examiner further rejected claim 25 under 35 U.S.C. 102(b) as being anticipated by Devany et al U.S. Patent No. 5,179,660. The Examiner asserts that the Devany reference anticipates claim 25 because it discloses a database system that comprises the storing of "centralized collection of geographically distributed information". However, claim 25 is directed to an article of manufacture comprising a web-enabled product that is used to provide real time clinical trial information to physicians. Further, claim 25 is directed to a web-enabled product that allows for means to check for the integrity of the clinical trial information. Devany et al. does not disclose or suggest an article of manufacture that allows the user to verify the data stored in the database. Rather, Devany discloses a system to minimize the information communicated over the network. The ability to check the integrity of clinical data is essential to the success of a clinical trial. Therefore, since the Devany reference does not disclose or suggest the claimed article of manufacture, it cannot anticipate the claimed invention. Therefore, reconsideration and withdrawal of this objection is respectfully requested.

The Examiner further rejected claim 25 under 35 U.S.C. 102(b) as being anticipated by Williams, Jr. U.S. Patent No. 4,868,866 [hereafter Williams]. The Examiner asserts that the Williams reference anticipates claim 25 because it discloses a database system that comprises the storing and distribution of "centralized collection of geographically distributed information". However, the present invention is directed to an article of manufacture comprising a web-enabled non-platform specific computer

product. Williams does not disclose or suggest an article of manufacture that is not platform specific. Rather, Williams discloses a broadcast data distribution system that is platform specific. As such a user would have to subscribe to the broadcast system before he would be able to view the data. As mentioned above, the claimed invention, in claim 25 is not platform specific, and a physician would not have to subscribe to a broadcast platform.

Further, Williams discloses an invention directed to an information distribution system for providing real-time and non-real-time data to an unlimited number of subscribers each having a receiving apparatus via a *one-way, non-interactive* broadcast data feed. However, the present invention is directed to an article of manufacture that allows both the sender and receiver to input and modify the transmitted data. A physician can add his own clinical trial information and send the data over the Internet. According to the Williams system, a user would be only able to view the data, and not add his own. Since the Williams reference does not disclose or suggest the present article of manufacture, it cannot anticipate the claimed invention. Therefore, reconsideration and withdrawal of this objection is respectfully requested.

Rejections Under 35 U.S.C. § 103

Claims 1-24 stand rejected under 35 U.S.C. § 103, as being obvious over JetForm in "JetForm(R) Announces First Java™-Based Electronic Forms Solution", in view of Williams (1989).

Claim 1 is directed to a web-based method that allows a user, at a remote site, to send data over the Internet and check the integrity of the data. The Williams reference

does not disclose a method where a subscriber (user) can send data over the Internet, the subscriber is only able to receive data via an apparatus, not input and transmit data. Further, while Williams does disclose a "second data verification module" the subscriber (user) cannot perform any verification of data as claimed in claim 1. The JetForm reference (cited both in the rejection statement and the discussion section) does not cure the above noted deficiency of Williams. Furthermore, the examiner does not suggest a reason for combining these two prior art references. Thus Applicants submit that the combination of Williams modified by JetForm cannot render obvious the claimed invention. Therefore, reconsideration and withdrawal of this rejection is respectfully requested.

Independent claim 11 is directed to a system that allows for a user to input information at a remote site. The Williams reference does not disclose or suggest a two-way interactive web-enable database system that allows both the sender and receiver to modify and input information transmitted. The Williams reference only allows subscribers at a remote site to view the information and not input information as stated in column 1, lines 10-15, "In particular, the invention is directed to an information distribution system for providing both real-time data and periodic (non-real-time) data to an unlimited number of subscribers each having receiving apparatus via a one-way, non-interactive broadcast data feed." The ability for a user (subscriber) to input data, at a remote site, is an integral aspect of the invention because users are able to share real-time accurate information with other users at any remote site.

Further, the Williams reference discloses a "second data verification module", however, the reference does not disclose a "...first verification means at the remote site

for verifying the information for accuracy as the information is being entered with the input means” (Claim 11). Moreover, the JetForm reference does not cure the above noted deficiencies of Williams. Thus Applicants submit that the combination of Williams modified by JetForm cannot render obvious claim 11. Therefore, reconsideration and withdrawal of this rejection is respectfully requested.

Claim 23 is directed towards a computer system for clinical trial data management that has two verification systems; a first verification system at the remote site, a second verification system at a centralized computer for verifying information received from the remote site. The Williams reference only discloses a “second data verification module”, and does not disclose or suggest a first verification system wherein the subscribers (physicians) can check the accuracy of the data inputted. Moreover, the JetForm reference does not cure the above noted deficiencies of Williams. Further, the examiner does not cite any prior art references that would suggest that it would be obvious to one of ordinary skill in the art at the time of the invention to provide the further checking of Williams as a checking of the data in relation to data already occurring in the database could be preformed which could not at the remote site computer.” Thus Applicants submit that the combination of Williams modified by JetForm cannot render obvious claim 23. Therefore, reconsideration and withdrawal of this rejection is respectfully requested.


### **CONCLUSION**

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants respectfully submit that the claims are in

condition for allowance. Further, Applicants earnestly solicit early notification of the same. If a discussion of the application would speed the prosecution of the application, the Examiner is invited to contact Applicant's representative at the address and phone number listed below.

Respectfully submitted,

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